



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1211]

Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions To Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry.” The guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with FDA’s revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus (HIV) infection. FDA is also recommending that these blood establishments make corresponding revisions to donor educational materials, donor history questionnaires and accompanying materials, along with revisions to donor requalification and product management procedures. The guidance announced in this notice finalizes the draft guidance of the same title issued January 2023. This guidance also supersedes the guidance entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry” dated April 2020 and updated August 2020.

DATES: The announcement of this guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on any guidance at any time as follows:

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2015-D-1211 for "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood

Products; Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance document to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Andrew Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a final guidance entitled “Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry.” This guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with FDA’s revised donor deferral recommendations for individuals with increased risk for transmitting HIV infection. FDA is also recommending that these blood establishments make corresponding revisions to donor educational materials, donor history questionnaires and accompanying materials, along with revisions to donor requalification and product management procedures.

In this guidance, based on FDA’s review of the available science, FDA recommends eliminating the screening questions specific to men who have sex with men (MSM) and women who have sex with MSM. Instead, FDA recommends assessing donor eligibility using the same individual risk-based questions relevant to HIV risk for every donor regardless of sex or gender. In addition, FDA recommends deferral of any individual taking medications to treat or prevent

HIV infection. FDA does not expect that implementation of these revised recommendations will be associated with any adverse effect on the safety or availability of the blood supply.

In the *Federal Register* of January 30, 2023 (88 FR 5894), FDA announced the availability of the draft guidance of the same title. FDA considered comments received on this draft guidance as the guidance was being finalized and revised the guidance as appropriate in response to the comments. For instance, we clarified that all donors, regardless of their sex or gender, will be asked the same screening questions with respect to HIV risk. We have provided additional information to explain why undetectable does not equal untransmissible for blood transfusion regarding medication used to treat or prevent HIV infection, and we added a recommendation that individuals should not stop taking their prescribed medication, including PrEP or PEP, in order to donate blood. In response to questions about deferral recommendations for anal sex, we clarified that scientific data demonstrate the risk of HIV infection is significantly greater for anal sex when compared to other sexual exposures. In response to comments requesting clarification on a screening question, we included examples of who a “new partner” may include. Additionally, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2023 and supersedes the guidance entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry” dated April 2020 and updated August 2020.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on evaluating donor eligibility using individual risk-based questions to reduce the risk of HIV transmission by blood and blood products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 606.121 and parts 610 and 630 have been approved under OMB control number 0910-0116; and the collections of information for consignee notification have been approved under OMB control number 0910-0681.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: May 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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